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| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/310,638 | HERMONA SOREQ ET AL | |
| | Examiner | Art Unit | |
| | Deborah Crouch, Ph.D. | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to filing of November 29, 2004.
2. ☒ The allowed claim(s) is/are 11-13, 17, 20, 23, 24 and 26.
3. ☒ The drawings filed on 12 May 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>3/2/05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. John P. White on March 2, 2005.

1. Please rewrite claims 11, 12 and 17:

11. A transgenic non-human mammal whose genome comprises a recombinant nucleic acid expression vector encoding a heterologous cholinesterase positioned under the regulatory control of a promoter functional in the mammary gland of the transgenic non-human mammal, said heterologous cholinesterase selected from the group consisting of:

- (a) wild-type human AChE;
- (b) wild-type human BChE;
- (c) variants of (a) and (b) having cholinesterase activity; and
- (d) wild-type insect ChEs,

wherein said heterologous cholinesterase is expressed in milk of said nonhuman mammal in detectable quantities.

12. The transgenic non-human mammal of claim 11, wherein the transgenic non-human mammal is a mouse.

17. The transgenic non-human mammal of claim 11, wherein the transgenic non-human mammal is female and wherein said promoter is a mammary gland specific promoter.

2. In claim 13. line 1, delete "animal" and insert -mammal-; and in line 2 delete "12" and insert -11--;

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4. In claim 23, line 2 delete "12" and insert --11--; and in line 4, delete "germ cells and/or somatic cells" and insert --milk--.
5. In claim 24, step (i), delete "providing the lactating" and insert --inducing lactation in the--.
6. In claim 26, line 1 delete "animal" and insert --mammal--.
7. Cancel claims 1-10, 15, 16, 21, 22 and 27 without prejudice or disclaimer for further prosecution in a continuing application.

Examiner's Comments:

1. The title has been changed to: --Transgenic Non-Human Mammals Producing a Cholinesterase in their Milk--.

The following is an examiner's statement of reasons for allowance: Applicant's arguments and amendments were persuasive for allowance. A review of the affidavits submitted by applicant November 29, 2004 provides a survey of the art of mammary gland bioreactor mammals at the time of filing. While the production of such mammals was well known and therefore enabled at the time of filing, there was no specific teaching, suggestion or motivation to produce the claimed mammals producing a heterologous cholinesterase in their milk.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

March 7, 2005